



Insurance and Indemnity

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Indemnity and Insurance





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Indemnity

- security or protection against a loss or other financial burden

Insurance

- an arrangement by which an entity undertakes to provide a guarantee of compensation for specified loss, damage, illness, or death in return for payment of a specified premium

VMIA Requirements

There is no requirement to seek approval from VMIA for any aspect of clinical trials.

- Please contact VMIA in the following situations:
 - If your organisation is involved in a First Time in Human Clinical trial (FTIH) and is required to provide an indemnity for the Independent Expert Reviewer.
 - To report a Suspected Unexpected Serious Adverse Reaction (SUSAR) which may cause harm and potentially lead to a claim. Please forward details to miclaims@vmia.vic.gov.au

Indemnity and Insurance

What are you covered for under the VMIA

Medical Indemnity Policy

- The Medical Indemnity Policy includes a definition of ‘Clinical trials and health and medical research’ and the definition of ‘Health Care Services’ includes ‘Clinical trials and health and medical research’ (Section 2, Definitions, pg. 4). This wording was effective from 2 October 2014.
 - **Health care services** means any care, treatment, counselling, advice, service or goods provided in respect of the physical or mental health of a patient or person, including **Clinical trials and health and medical research activities** unless otherwise excluded by this policy.
 - **Clinical trials and health and medical research** means participation in trials or research projects, that have been approved by a properly constituted Human Research Ethics Committee in accordance with National Health and Medical Research Council guidelines and where such trial and/or health and medical research has been conducted in accordance with any conditions or approvals made by such Human Research Ethics Committee

Insurance and Indemnity

What are you covered for under the VMIA

Public and Products Liability

-Healthcare

- Any care, treatment, service or goods provided in respect of the physical or mental health of a person, including the conduct of Clinical trials and health and medical research activities.

-Clinical trials and health and medical research

- participation in trials or research projects, that have been approved by a properly constituted Human Research Ethics Committee in accordance with National Health and Medical Research Council guidelines and where such trial and/or health and medical research has been conducted in accordance with any conditions or approvals made by such Human Research Ethics Committee.

-Public and Products liability is particularly important in investigator initiated clinical trials when the protocol and investigational product has been developed by the hospital

-Commercial sponsors usually have a PPL policy in place as the clinical trials insurance for the investigational product

Medicines Australia Std Form of Indemnity Exclusions

The above indemnity by the Sponsor will not apply to any such claim or proceeding referred to in paragraph 3:

- (1) to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Indemnified;
- (2) to the extent that such personal injury (including death) is caused by the failure of the Indemnified Party, its employees, or agents to conduct the Study strictly in accordance with the Protocol;

Insurance Certificate

A valid certificate of insurance needs to be evidenced:

- Ideally:
 - Local sponsor is a named insured
 - Policy specifically states that it covers clinical trials and may even reference the Protocol number
 - \$10mil in the annual aggregate with \$20K deductible
 - Underwriter is a credible institute
 - Policy is for the duration of the trial
 - Some companies can self insure for an initial amount of 1-10mil AUD
- If compensation claims exceed the insurance policy limit, then the company is directly liable for claims above this amount. This becomes an issue if a company becomes insolvent and can not meet its obligations in this regard.

Best Insurance Policy

- Use the Standard MA Agreements with pre-approved Schedule 7 or 4
- Be aware of territorial limits of the VMIA policy
- *3.10. Any legal liability of whatever nature directly or indirectly arising:*
 - *i) out of any act, error or omission committed or alleged to have been committed within the territorial limits of the United States of America, its territories or protectorates, or Canada; or*
 - *ii) in accordance with and pursuant to the laws of the United States of America, or Canada.*
- *3.11. Any Claim brought against the Insured in a court of law outside the Commonwealth of Australia, Papua New Guinea or New Zealand, or in respect of any action brought in a court of law within the Commonwealth of Australia, Papua New Guinea or New Zealand to enforce a foreign judgment whether by way of reciprocal agreement or otherwise.*
- Ensure that what is being undertaken constitutes part of the organisation's health service delivery that are carried out by staff that are authorised to do so.

Thank you